

Chapter 11

Dispensing Oral Drugs

The dispensing function provides oral drugs to protect the public from a biological threat. It is the most complex of all National Pharmaceutical Stockpile (NPS) planning functions. It includes the following activities:

- ◆ Set up and operate a highly efficient operation that serves thousands, perhaps hundreds of thousands, or even millions of people quickly before they become symptomatic;
- ◆ Locate and coordinate the use of highly skilled, but relatively scarce pharmacists, doctors, and nurses to staff and manage dispensing operations;
- ◆ Train and organize many volunteers to perform the majority of dispensing site functions;
- ◆ Overcome routine legal/regulatory barriers that prevent non-pharmacists from handing out prescription drugs during a large-scale emergency;
- ◆ Isolate symptomatic individuals and transport them to treatment centers; and
- ◆ Provide the public comprehensive, accurate, reassuring information about community efforts to protect them from a threat.

We divide our discussion into the following sections:

- ◆ Site selection criteria
- ◆ Efficient dispensing-site design
- ◆ Operational issues
- ◆ Command and control support
- ◆ Protection of those who cannot use dispensing sites
- ◆ Public information and communications.

SITE SELECTION CRITERIA

For dispensing to be effective, it must have enough capacity to protect your potentially affected population in time to prevent the onset of symptoms. When creating your plan, you should assume a worst-case scenario and plan sufficient sites with sufficient capacity to provide prophylaxis to your entire community. If you plan for a wide-scale event, it will be easy to scale your plan down for a more limited event. It will be extraordinarily difficult, however, to scale it up if you have planned only for a limited event.

We recommend that you consider the following factors when determining the number and location of dispensing sites:

- ◆ *Scale, type, and location of an attack.* These factors determine the number of people exposed (or worried about exposure) and thus the number and location of people you must protect within a specific period.
- ◆ *Number of sites.* More sites
 - make it easier for the public to get to the sites (shorter driving distances, less congestion, possibility of walking to the sites);
 - reduce the length of the lines at sites;
 - reduce the time to get protective drugs; and
 - reduce the anxiety of those who must wait in line for the drugs.

On the other hand, more sites

- require more security to protect sites, delivery vehicles, and drivers, and
- require more staff members, particularly pharmacists, doctors, and nurses.
- ◆ *Size of facilities.* Compared with having several small sites, larger but fewer sites
 - may be able to process more people with the same number of pharmacists, nurses, and doctors, but
 - may pose a bigger crowd control problem because they concentrate more worried, frustrated people in one place.
- ◆ *Operating hours.* Each site must be open 24 hours a day when the public must receive their first protective regimen. Around-the-clock operation will require a large staff.

- ◆ *Dispersed locations.* To minimize traffic congestion, the public should be able to walk to the sites if possible. Sites should be in each community to preclude the perception of favoritism for parts of the population.
- ◆ *Familiar locations.* The sites should be easy to find.
- ◆ *Accessibility.* People should be able to use public transportation or private auto. (See our discussion later in the chapter on transporting the public during mass prophylaxis campaigns.)
- ◆ *Physical characteristics.* Sites must be big enough to handle large numbers of people under cover and out of the weather. Each site should have the following characteristics:
 - Heat and air conditioning to maintain temperatures at controlled room temperature, which the U.S. Pharmacopoeia defines as “the usual and customary working environment of 20°C to 25°C (68°–77°F) that allows for brief deviations between 15°C and 30°C (59°–86°F) that are experienced in pharmacies, hospitals, and warehouses”¹;
 - Adequate bathrooms, water, and electricity;
 - A loading area (for receipt of supplies);
 - Space for parking at or near the sites; and
 - Space for landing a helicopter if you use that distribution option.

As you design your dispensing site network, consider public and commercial options. The former include public schools, universities, community recreation centers, firehouses, polling places, and armories and other buildings under National Guard control. The advantage of most public places is that they are familiar to the community and often within walking distance. Polling places are particularly attractive because the public uses them to vote, and they come with a cadre of election volunteers to staff them.

Commercial dispensing options include stores where the public already fills their routine prescriptions. Many of these facilities are part of large regional or national chains that may be willing to support the community in an emergency. Some have freestanding pharmacy outlets with drive-through windows. Most have good parking facilities and convenient access. Their pharmacists could set up tables in or outside the store, work with community volunteers, and process many citizens. One additional advantage to commercial facilities is that pharmaceutical distributors and other commercial delivery vehicles already support these locations and could be part of your distribution network. A potential drawback to them is that they may not have enough staff to operate 24 hours a day.

¹ U.S. Pharmacopoeia, *Practitioner Reporting*, No. 40, Revised 6/94, “Storage Definitions.”

Some states and cities have hesitated to use sites that the public frequents (schools, malls, etc.) because they fear that a contagious threat (plague, smallpox) would make these sites unusable until authorities could decontaminate them. Yet, the convenience of these locations is precisely what makes them so attractive as dispensing sites. As a planner, you must balance the necessity of protecting the public quickly during an emergency with the desirability of returning the public to normal daily life after an emergency.

EFFICIENT DISPENSING-SITE DESIGN

The number of people your network of dispensing sites can protect per hour is a measure of its efficiency. If your plan anticipates having to protect 100,000 people in 3 days and your dispensing sites can only handle 25,000 people per day, you need to improve each site's efficiency or increase the number of sites. This section discusses processes and staff organization at dispensing sites that will make them more efficient.

Even if pharmacists, doctors, and nurses are in short supply, you can significantly improve a site's efficiency by having health professionals supervise volunteers who do most of the work. For example, every site will probably provide people who come to the dispensing site with information about the threat, the protective drug regimen they will receive, and the process for getting their medication. A volunteer with a well-written script or a video can provide that information, freeing a pharmacist to perform other tasks.

Process

To increase the efficiency of your dispensing sites, consider taking the following actions:

- ◆ *Plan for a wide-scale attack.* Design your dispensing operation to process many people quickly for a large-scale attack. You can easily scale an efficient process down for a smaller event, but it will be very difficult to scale an inefficient process up to process many people in a large-scale event.
- ◆ *Have regulatory waivers available for the governor to sign.* Ensure that individuals other than pharmacists are able to hand out prescription drugs at your sites during an emergency. Virtually every state has pharmacy laws that regulate who may dispense prescription drugs. Where such laws are restrictive, you need to have waivers ready for your governor to sign that will allow volunteers under a pharmacist's supervision to hand out oral drugs during an emergency.
- ◆ *Prepare multi-language signs, handouts, posters, and videotapes.* Those materials should
 - direct the movement of people,

- keep them moving,
- keep them occupied,
- let them know what is happening, and
- tell them what they need to know about the drugs they will receive.

Not everyone will listen, watch, or read the information you provide, but those who do will probably require less attention, making your process more efficient.

- ◆ *Minimize the use of any staff.* Design a process that directs the movement of people with methods such as multi-language signage noted above and portable crowd control barriers such as those used by airlines in ticket lines.
- ◆ *Simplify health information forms.* Make the forms threat specific to reduce the time for the public to understand and complete them.
- ◆ *Reduce the number of stops to get drugs.* If a person diverts from the line for some reason—for example, check for symptoms, weigh children, or process regimen requests for family members who are not present—make sure they rejoin it at an appropriate point and do not have to start at the beginning. If possible, issue their regimens at the end of the line to which they diverted.
- ◆ *Ensure adequate support.* Make sure the site has the following items:
 - Equipment—label printing equipment (computers, printers, and label stock);
 - Facilities—tables, chairs, lane roping, toilets, drinking water (important particularly during hot months), chairs for the young and elderly, and wheel chairs;
 - Supplies—pens, pencils, paper, forms, and bottled water; and
 - Specialized items—scales for weighing children, mixing equipment for pediatric portions, etc.

Staff Assignments

Staff members or volunteers will be needed to do the following:

- ◆ Orient the public (video or volunteer with a script);

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- ◆ Examine and redirect symptomatic people to treatment (healthcare professional);
 - ◆ Weigh children under age 5 (volunteer);
 - ◆ Replenish and reorder supplies such as labels, unit-of-use drugs, and consumable items such as pens, paper, and toilet paper (volunteer with minimal training);
 - ◆ Explain dispensing-site procedures and policies, for example, whether you allow one adult to pick up drugs for an entire family and the maximum number of regimens you will provide (volunteer with training and a script);
 - ◆ Hand out name/address/phone/health history (NAPH) forms and instruct people on how to complete them (volunteer with training);
 - ◆ Educate and orient people standing in line (volunteer with a script);
 - ◆ Explain various information, including
 - drugs people will receive including any pediatric medicines for children (health professional or video),
 - importance of adhering to regimen instructions (volunteer with a script),
 - danger of overmedicating (volunteer with script), and
 - date to return for additional regimens (volunteer).
 - ◆ Check completion of NAPH forms for all people in line and those who are not present if you authorize adults to pick up medicines for others such as family members and senior citizens (volunteer);
 - ◆ Interpret directions for people who do not speak English or are hearing impaired, deaf, or illiterate (interpreter, volunteer, professional interpreter, or multi-language videos);
 - ◆ Provide technical expertise such as answering questions or prescribing an alternate drug regimen based on the patient's medical history form for conditions such as allergies, pregnancy, breast-feeding, and adverse reactions to existing medications (medical and/or pharmacy professional);

- ◆ Distribute regimens, which includes
 - annotating required additional information on the drug label (prescription number, drug, lot, etc.) and recording the drug regimen on the person's NAPH form (see section below on labeling under operational issues to understand how our labels support this action) (volunteer with professional supervision);
 - collecting NAPH forms (volunteer); and
 - providing patient information sheets that explain the importance of complying with the drug regimen, the danger of overmedicating, and the date to return for the next regimen (volunteer with professional supervision).
- ◆ Provide physical security for traffic and crowd control and protection of NPS personnel, equipment, and materiel (law enforcement);
- ◆ Manage dispensing-site operations and serve as the problem solver of last resort (public health person).

OPERATIONAL ISSUES

This section discusses operational issues with dispensing that your plan needs to address.

Staffing

A large-scale event will require a lot of dispensing sites to process the public quickly enough to prevent the onset of symptoms. Your plan must identify enough staff with the proper training to operate the number of sites that you will need. We separate staff into three categories:

- ◆ *Health professionals.* This group includes doctors, nurses, and pharmacists. Contact state agencies that license these professionals to identify individuals in other parts of the state that might help. The Health and Human Services Emergency Coordinator for your state may be able to suggest additional sources. You may also want to talk to commercial pharmacies about using their pharmacists during an emergency.
- ◆ *Trained volunteers.* This group includes the following:
 - Interpreters. Potential sources for interpreters include universities, ethnic organizations, and churches.

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- People who know sign language. Potential sources for individuals who can converse with the deaf in sign language include local schools for the deaf, associations for the hearing impaired, and the Internet (search for “Hearing impaired” and “American Sign Language”).
 - Generalists that have provided assistance before. Contact the American Red Cross. It is part of every community in the nation and has a commendable record of support during troubled times. As we go to press, we are working on a Statement of Understanding with the American Red Cross that will facilitate local chapter support for an NPS deployment to
 - provide trucks and drivers to distribute the NPS to treatment and dispensing locations;
 - distribute NPS oral drugs to people who cannot use dispensing sites, including prison inmates, nursing home patients, and people receiving home healthcare;
 - support emergency communications;
 - supply dispensing sites with equipment and consumable items;
 - staff various functions at dispensing sites;
 - assist with dispensing-site administration and logistic activities;
 - help gather treatment facility data on patient estimates and medical supplies; and
 - assist with public information campaigns.
 - ◆ *Untrained volunteers.* Civic and fraternal organizations are good contacts for recruiting volunteers.

Receipt of NPS Materiel

Dispensing sites must maintain the temperature of the drugs they provide the public between 68°F and 77°F (with brief deviations between 59°F and 86°F) to ensure their potency (see reference in Chapter 7). That means that during hot or cold times of the year, dispensing staffs cannot leave deliveries outside (see discussion in Chapter 7 on temperature control of NPS materiel).

Transporting the Public to Dispensing Sites

In the absence of an alternative, many people will try to drive to a dispensing site during a large-scale emergency. The resulting congestion and parking problems, combined with the worry of contracting a life-threatening disease and the frustration and anxiety while waiting in a long dispensing line may interfere with your ability to dispense protective medications.

To avert congestion and frustration, you may want to ask your local bus service to provide free transportation from every bus stop to the nearest dispensing site during a large-scale emergency. That action would allow you to move large numbers of people to the dispensing site by simply telling the public to go to any bus stop.

Labeling of Prescriptions

State and federal regulations specify the information that you must provide on the drug label and the patient information sheet that you give the public when you dispense prophylactic medicines. For example, the Federal Drug Administration (FDA) requires that the label include

- ◆ drug name, strength, and quantity;
- ◆ directions for use;
- ◆ name and address of the dispensing location;
- ◆ serial number of the prescription;
- ◆ date of the prescription; and
- ◆ name of the prescriber.

The information on the labels that we provide will depend on when we prepare them. Labels on the unit-of-use bottles that our vendor prepares will have only the drug name, strength, quantity, lot number, and unique prescription number. Your dispensing sites must provide the prescribing agency, the prescriber, and a 24-hour telephone number to call with questions.

By contrast, the labels for drugs that you may have to repackage locally will have more information:

- ◆ Packaging machine labels. Our industrial, high-volume-packaging machines will label each regimen bag in English with the information that FDA requires for
 - doxycycline for anthrax, plague, or tularemia,
 - ciprofloxacin for anthrax, and

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- ciprofloxacin as an investigational new drug (IND) for tularemia.

Each of the above labels will be in English and contain the following information, which we will add when we set up the packaging medicines:

- Official health agency name, city, and state
- Prescriber's name
- Prescription date
- Quantity of pills in the regimen
- Prescription number
- Lot number of the drug
- Number for 24-hour answered telephone line
- Patient's name (left blank).

Your dispensing sites will have to annotate the patient's name on these labels when they dispense the drug or have the recipient write his or her name on the label.

General purpose labels. We provide a CD with software that you can use with a computer to print multi-language labels (English plus 47 other languages) for regimens that you produce with the tablet counting machines and volumetric devices in a 12-hour Push Package. You also can use this software to print labels in another language and apply them to the reverse side of bags filled by our high-volume packaging machines.

When you use our software to create a label in a language other than English, you will have to edit the English version of the label and then print two labels, the edited one in English and a second in another language. You will apply the English label on the front of a regimen bag and the foreign language label on the rear. The English version will contain FDA-required variable information such as prescribing agency, city and state, 24-hour number, prescriber, prescription number, prescription date, and number of tablets in the regimen. Labels in other languages only contain instructions for taking the drug and precautions for using it. You cannot edit the foreign language labels.

We designed the CD to print labels on plain Avery® 5395 Name Badge Labels or its equivalent. We chose this label for several reasons. It holds all required prescription information in English.

Its font is readable, and it fits the plastic prescription bags that come with the 12-hour Push Pack and the high-volume packaging machines. Unfortunately, the label is too large to fit on the unit-of-use regimen bottles. Instead, we suggest that you affix it to the back of the patient information sheet that you give people with their unit-of-use regimen.

Patient Information Sheets

Our CD also includes electronic versions of patient information sheets, in English and 47 languages, for each drug and threat. These appear as electronic templates on the CD in a special print format called Adobe Acrobat®. The templates do not require special fonts. They allow you to insert the dispenser's name, the prescriber's name (e.g., State Health Department Director), and a 24-hour phone number for questions. The CD also contains formats for printing dosing instructions and cautionary language in multiple languages, which you cannot edit.

Reproduction of Labels and Patient Information Sheets

Each state has received a copy of our CD, which it can replicate for each dispensing site that may have to print labels and patient information sheets. As an alternative to having a printer and computer at each site, you can establish a contingency contract with a large photocopy firm to store the contents of the CD, your NAPH form, and other event-related forms. During an emergency, the firm could replicate whatever forms you needed and deliver them to dispensing and other locations.

Tracking of Drugs and Drug Recipients

Tracking drugs and drug recipients is a process that

- ◆ starts with the completion of an NAPH form for everyone who receives protective medicines, including those in line and those (children and family members who are ill or incapacitated) for whom people in line will pick up regimens;
- ◆ uses health history to provide the right drug; and
- ◆ records, on the NAPH form, the information about the drug that a person receives and the action associated with dispensing it to them (date, time, location, dispenser, and especially the prescription number).

Recording this information allows you to

- ◆ track possible contamination or adulteration of drug lots,
- ◆ investigate serious adverse reactions (required by FDA) to investigational new drugs such as ciprofloxacin for tularemia or amoxicillin for anthrax,

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- ◆ identify the failure of prophylaxis when individuals contract a disease in spite of having taken oral drugs to prevent it, and
 - ◆ inform recipients of FDA drug recalls for additional or different drugs in the event of prophylaxis failure.

NAME/ADDRESS/PHONE/HEALTH HISTORY

So dispensing can provide the correct drug in the right strength, you must get reliable NAPH information from those in line, which is not always easy. Language barriers, deafness, blindness, and illiteracy complicate the process. A family member who picks up medicines for other family members (if you allow that practice) may not have all of the information you need to accurately prescribe for each member (e.g., a child's weight). Some in line, such as illegal aliens, may lie because they fear the consequence of providing accurate information.

You need to design a set of NAPH forms that are short, simple, and threat specific. (Appendix L is an example of a form specific to anthrax.) Use contingency contracts with a local photocopy firm that can reproduce forms rapidly during an emergency. You also need to provide instructions for completing the NAPH form so that its completion will not slow the processing of people in line during a large-scale event.

DRUG RECIPIENT AND DRUG-RELATED DATA

The key to tracking a drug, its lot, and its recipient is the drug's unique prescription number. Annotating that number on the patient's NAPH form will allow you to identify every patient that received a particular drug/lot combination.

We have designed our drug labels to facilitate the manual capture of drug, lot, and recipient information:

- ◆ *Unit-of-use bottles* have two tabs on their side. Each tab contains the drug name, expiration date, lot number, and a unique prescription number. By affixing one of the tabs to a recipient's NAPH form, you will record the drug and its lot that each recipient receives. If the person who dispenses the drug further annotates the form with their identification, date, time, and location, you will be able to tell where, when, and how a recipient received the drug.
- ◆ *Packaging machine labels* have a tear-off tab on the bottom of the label that contains the same unique prescription number as the label itself. If you tear off this tab and staple it to the recipient's NAPH form, you will have a link between a drug, its lot, and its recipient.

- ◆ *CD-printed labels* do not have a tab but dispensing could stamp a unique prescription number on the NAPH form and the drug label. To accomplish that, we provide 30 number-stamping machines in each 12-hour Push Package.² The machines are hand-held imprinters that will stamp a 7-digit number the number of times that you specify. For example, you can set the machine to increment its number after stamping the number twice. That would allow you to stamp the NAPH form and the drug label with the same number before the stamping machine incremented its number. By assigning persons who hand out drugs at a dispensing site a block of numbers for their stamping machines, management will know the recipients that got specific drugs, at a specific dispensing site, from a specific person.

AUTOMATION OF NAPH/DRUG INFORMATION

Several states have asked us about automating the recording of NAPH and drug information as people come through the dispensing process. While immediate access to the data might be helpful, we are concerned that the effort to enter data while people are in line will slow the movement of people through the line. We agree that there would be some value to knowing that someone had already gone through another dispensing line once and thus should not be able to get more drugs a second time. However, the effort to get that knowledge (i.e., keying in data while someone is in line and sharing it among dispensing sites when communications may not be reliable) makes that result unlikely or probably unreliable.

Instead, we suggest that you investigate the possibility of contracting for the key entry of recipient/drug data from annotated NAPH forms. Each dispensing site would forward its annotated NAPH forms to a contractor. Within a day or two, dispensing would have an automated way of finding recipients who received specific drug/lot combinations. The data would also allow the notification of specific recipients through the mail or by using automated dialing machines with a prerecorded message. Some state vaccine programs already use automated dialers to inform parents that their children need immunizations. You may want to ask your state immunization program how they notify parents.

Ultimately, the accuracy of patient/drug records will depend on the following basic actions

- ◆ Ensuring that each dispensing site has adequate supplies of NAPH forms and the means for recipients to complete them (pencils, clipboards, clear instructions, etc);

² GBC Bates Multiple Movement Numbering Machine, Catalog Number BAT9820321, type size A, 7 wheels, Model Number 7AMULT, approximate cost \$230. See picture at http://www.quartetgbc.com/products/desk_access/products/numberingmachines.html

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- ◆ Providing a number-stamping machine (and the training to use it) to each staff member who distributes regimens; and
 - ◆ Assigning a block of prescription numbers to each dispensing site and person who hands out drugs to identify the regimen distributor and the dispensing site.

Protecting Undocumented Aliens

Several states have large populations of undocumented aliens whom they must protect in an emergency. For these individuals, the fear of arrest and deportation may be greater than the fear of getting a disease from a terrorist attack. You should develop an effective campaign to convince undocumented aliens of the importance of taking their families to a dispensing site.

California is attempting to reach its undocumented population with an approach that it used during the North Ridge earthquake several years ago. It asked officials from consulates whose nations represented the bulk of California's undocumented population to issue reassuring messages through mass media outlets that undocumented aliens use for their information. You may want to consider a similar approach.

Pediatric Prophylaxis

Each 12-hour Push Package contains quantities of ciprofloxacin oral suspension, doxycycline oral suspension, and doxycycline pediatric syrup for the treatment of children and adults who have trouble swallowing tablets. The ciprofloxacin oral suspension will provide 4,000 people 5 days of prophylaxis. Doxycycline pediatric syrup will provide 7 days. The last is adequate for protecting against plague, but insufficient for a 14-day course against tularemia or a 60-day course against anthrax.

We provide limited amounts of these items because of

- ◆ high cost,
- ◆ relatively short shelf life,
- ◆ limited use in the private sector (thus making it difficult to rotate), and
- ◆ difficulty of predicting the numbers of people who might need these drugs.

As an alternative, we recommend you consider the following:

- ◆ *Using the Push Package's 25,000 10-day regimens of amoxicillin chewable tablets.* These are in the Push Package primarily to protect pregnant women, people who are allergic to ciprofloxacin and doxycycline, and children against anthrax. Children between the ages of 2 to 5 can chew these tablets. Younger children will readily take them if you crush and mix them in a food such as applesauce. The softness of the tablet and a groove down its middle make it easy to divide into the smaller portions dictated by the child's weight. The main drawback to any use of amoxicillin for anthrax is that it is not a labeled use. You must administer it as an investigational new drug, get signed consent forms, and monitor adverse reactions.
- ◆ *Converting ciprofloxacin and doxycycline tablets into oral suspension.* While all pharmacists learn how to compound drugs, few do it frequently enough to be proficient. However, every community has a small number of pharmacies that specialize in compounding. You can find them by looking in the Yellow Pages® or by contacting your State Board of Pharmacy. We suggest that you establish contingency contracts with these pharmacies to increase your ability to protect more individuals with oral suspensions during a terrorist event. (Appendix M contains directions for creating these suspensions.)

Off-Label Use of NPS Drugs

All of the drugs in the NPS have long-established safety and efficacy records. However, some are not FDA-labeled to treat specific agents released by a terrorist. We are working with the FDA to establish a streamlined process that will qualify these drugs and save you the trouble of using them as investigational new drugs. In the interim, we recommend that you establish an effective patient tracking capability and train your dispensing staff to administer consent forms that meet FDA's IND requirements. We will add multi-language IND consent forms for off-labeled use of antibiotics to a future release of our multi-language CD.

COMMAND AND CONTROL SUPPORT

Before dispensing can begin, the command and control function must provide definitive guidance on the following:

- ◆ *Multiple versus individual regimens.* A multiple regimen policy allows an adult to pick up medicines for other members in a family who are sick or incapacitated. A multiple regimen policy potentially shortens dispensing lines, gets people their drugs faster, and reduces public frustration and the staff that must deal with it. It also allows some individuals to acquire more drugs than they should have, but its benefits far outweigh that possibility.

If you allow multiple regimen pickups, your public health information campaign needs to tell the public the information they need to bring to dispensing for each family member who is sick, incapacitated, or otherwise unable to report in person. If you want to try to limit abuse, you may also want to consider the type of evidence they should bring to justify the number of regimens they request. For instance, one state in a recent functional exercise decided to distribute up to five regimens without question but briefly interviewed those who requested more. This routine might discourage abuse, but it would also probably slow the movement of persons through a dispensing line unless you rerouted them to a special interview line.

- ◆ *Distributing agency, prescriber, and 24-hour information number.* Dispensing must put this information on labels or patient information sheets to comply with FDA labeling regulations. The state health department is the likely choice for the prescribing agency, particularly in regional areas that include several jurisdictions. The 24-hour information number could belong to any official health or emergency response agency that has multiple call capability on one number. The prescriber is likely to be the state health officer (SHO) or the highest-ranking physician in that agency if the SHO does not have a medical license. Clearly, it is important to have the above information long before an event so you can be ready to print patient information sheets on the various NPS drugs and drug labels.
- ◆ *Prophylactic regimens.* State/local medical authorities need to consider unit-of-use regimens in the NPS before they decide how to treat various biological threats. We supply labeled, unit-of-use, 10-day regimens that require no repackaging for dispensing. If state/local (S/L) medical authorities treat with any other regimen, they will force the repackaging of bulk oral drugs in the NPS and may seriously affect the S/L ability to respond quickly to a large-scale event.

We intentionally designed the regimens in the NPS to begin prophylactic treatment for anthrax, the worst-case scenario. We recognize that they contain 3 days more product than the treatment for plague but 4 days less than the treatment for tularemia. If you have to treat tularemia, we will provide additional 10-day regimens to complete a 14-day prophylaxis.

PROTECTION OF THOSE WHO CANNOT USE DISPENSING SITES

Every community will have groups of people who will not be able to use dispensing sites:

- ◆ Inmates of a corrections system (jails, prisons, juvenile detention facilities),

- ◆ Patients in nursing homes and other long-term care institutions,
- ◆ Patients in hospitals for reasons not related to the terrorist threat, and
- ◆ Immobile patients who get care at home through local home healthcare service providers.

Your plan needs to identify methods for providing prophylactic medicines to these individuals. Fortunately, many of them receive medical care from some type of healthcare facility. We recommend that you identify those facilities, plan your distribution system to deliver supplies of oral drugs to them, and work with them to provide prophylaxis to the individuals they serve.

PUBLIC INFORMATION AND COMMUNICATIONS

State and Local Health Communications Plan Support for the NPS

During a large-scale emergency, public fear and anxiety may impair your ability to distribute and dispense prophylaxis to those who really need it. An effective health communications plan that informs and reassures the public will reduce fear and anxiety and will be crucial to earning public confidence and cooperation.

When writing the dispensing section of your NPS plan, it is imperative that you make sure that the health communications plan within your S/L all-hazards or bioterrorism response plan contains comprehensive, accurate, reassuring information about the threat; dispensing efforts to protect the potentially exposed; and treatment efforts to care for the sick.

S/L public information officers and health educators are key to the successful effort to inform the public. They should be active participants in the creation of the health communications planning portion of your S/L all-hazards or bioterrorism response plan. They routinely consider language barriers, cultural sensitivities, hearing and sight impairment, and the ways that population groups get their information (TV, radio, church) to plan and create messages and information that effectively inform the public.

To create an effective health communications plan, information officers or health educators must start long before an emergency to work with health professionals, the media, and other groups to prepare multi-language messages and information that are threat and incident specific. Threat-specific messages tell people specific information about the disease, the protective drug regimens that the S/L government will provide to protect them, and the routine that they should expect when they go to a dispensing site. Incident-specific messages tell people who are potentially exposed where they must go for prophylactic medications if they are well, and where they need to go if they are sick.

An effective health communications plan will have messages and information materials prepared before an emergency so that authorities can quickly add incident-specific data at the onset of an emergency. The number of dispensing and treatment locations, for instance, will depend upon the scale and type of threat. A large-scale threat will require more dispensing sites, but if contagion is a concern, the number of treatment centers may be limited to avoid spreading the disease. Public information officers will need to know where the active dispensing and treatment locations are before they can effectively inform the public.

Public information officers or health educators also need to work with the media before an event to discuss the dissemination of information and messages. In addition to the important task of broadcasting health messages to the public, the media should be able to suggest ways to present and deliver the information so that target population groups understand and listen to it.

When completed, your health communications plan should include the following:

- ◆ Multi-language text of all documents used to inform the public during an emergency. These include TV and radio public information announcements and the informational materials, forms, scripts, and videos that dispensing uses to issue prophylaxis to the public;
- ◆ Storage location of all informational material (including electronic versions);
- ◆ Methods for reproducing and disseminating informational materials during an emergency; and
- ◆ Specific communication channels, partnerships, and staffing pools that support public information release, reproduction, and dissemination. The last should include volunteers or contract professionals to
 - serve as on-site interpreters for people who do not speak English, are hearing impaired, or are deaf, and
 - assist with public information campaigns, printing needs, and on-site public information assistance.

Your health communications plan, materials, and messages should contain the following information about the NPS Program:

- ◆ *The agent and its threat to the public.* The particulars of the event will affect how many people seek treatment at dispensing sites and treatment centers. This information will determine how much NPS materiel and information about the NPS that you will need to provide those locations. The information should answer these questions:
 - Is the agent contagious?

- Who should be concerned about exposure?
- Who should seek preventive treatment at dispensing sites and who should seek symptomatic treatment at treatment centers?
- ◆ *Directions to and information about dispensing and treatment locations.* This information will affect the use of specific locations and the amount of NPS materiel and the number of deliveries of that materiel that you make to specific locations. The information should answer these questions:
 - When will the dispensing operation start and what hours will it be open?
 - Where is the nearest dispensing site?
 - What is the best street access to each dispensing site?
 - Where should the public park at each dispensing site if it drives?
 - What is the best way to get to the dispensing site (walk, use public transportation, drive)?
 - What is the dispensing process?
 - What forms of identification are needed?
 - What information is needed to pick up medications for other family members?
 - Children: weight, age, health information, drug allergies, current medications
 - Adults: health information, drug allergies, current medications.
- ◆ *Information about the drugs the public will receive.* The information should include the following:
 - *Reasons for using specific drugs or changing drug regimens.* The cultural and ethnic sensitivity with which you provide the latter information is important to ensure that neighborhoods do not think others are getting favorable treatment when they receive different drugs. This information will affect the amount of specific drugs that you have to provide to dispensing and treatment locations. It will also affect the public's acceptance of those drugs.

During anthrax attacks in one area during the fall 2001, health authorities put at-risk individuals on ciprofloxacin until they determined that doxycycline was effective. After they made that determination,

the authorities put subsequent at-risk individuals on doxycycline to eliminate drug reaction problems from ciprofloxacin and to reduce cost. In their rush to protect all citizens, however, authorities failed to adequately explain their reasons for changing drugs. The resultant outcry forced public health officials to use their valuable time dealing with public complaints rather than protecting the public.

- *Importance of taking medication.* This information must stress the importance of taking all of a prescribed regimen (e.g., 60 days of doxycycline for anthrax). This information affects the demand for NPS materiel and minimizes the likelihood of more people becoming symptomatic.

Adherence is a well-known problem and will be especially challenging during an emergency if the treatment regimen is long, the prescribed drugs cause unpleasant side effects, and disease outbreaks stop before the public finishes its regimen.

After anthrax attacks in the fall 2001, CDC surveyed those who received prophylactic drugs against the disease. In spite of initial counseling and strong local appeals that encouraged these individuals to finish the 60-day regimen, we found that only 45 percent of them adhered to the regimen. Their reasons for sporadic or discontinued use included drug side effects and the perception that they were no longer at risk of getting anthrax.

- *Danger of overmedicating.* This information focuses on dispelling the notion that if two doses per day are good, four or six must be better. Its goal is to reduce the demand for NPS materiel by discouraging individuals from picking up drugs from multiple dispensing sites. A secondary goal is to minimize the possibility that some individuals will take more of a regimen than is safe.

State and Local Health Communications Plan Support for the NPS

Recently CDC awarded cooperative agreement funds to your state for response to Bioterrorism. Part of those funds supports the improvement of health communications during emergencies. We recommend that you contact the state office that is managing Focus Area F of the cooperative agreement to request help meeting your NPS-related health communications needs.

COMPLETION OF PLANNING

This chapter discusses the process for dispensing oral drugs to protect the public against a biological threat. Appendix B contains a thorough checklist of actions that you should consider for inclusion in this section of your plan. At a minimum, your plan should include

- ◆ the criteria for selecting the number and location of dispensing sites;
- ◆ the design of dispensing sites to serve the public as quickly as possible with a minimum of professional staff members;
- ◆ a plan that addresses operational issues such as labeling dispensed drugs, recording drug and patient information, protecting undocumented aliens, using and training volunteers, investigating new drug procedures, and preparing pediatric medications;
- ◆ a plan for protecting those who cannot use dispensing sites; and
- ◆ the information that needs to be in a community health communications plan to inform the public about the threat, dispensing efforts to protect those who are a-symptomatic, and treatment efforts to treat the sick.

